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Timothy G.J. Ehr

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MILLER, MATTHIAS & HULL
ONE NORTH FRANKLIN STREET
SUITE 2350
CHICAGO, IL 60606

EXAMINER

FOREMAN, JONATHAN M

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/027,154
Filing Date: December 20, 2001
Appellant(s): EHR ET AL.

MAILED
DEC 12 2007
Group 3700

Thomas A. Miller
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/19/07 appealing from the Office action mailed 6/22/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,168,703	Kenigsberg	9-1979
6,259,938	Zarychta et al.	7-2001
2002/0049402	Peacock, III et al.	4-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,168,703 to Kenigsberg in view of U.S. Patent Application No. 2002/0049402 to Peacock, III et al.

In regard to claims 10, 13 and 16, Kenigsberg discloses an elongated tube (22) including an opening and a closed distal end (Col. 3, lines 22 – 24), the tube being received in a tubular sheath (Col. 3, lines 18 – 20), the tubular sheath (12) having at least two spaced apart openings (20) in a sidewall thereof, the tube being slidable within the sheath to allow the opening of the tube to be aligned with the openings of the sheath (Col. 4, lines 57 – 64), the proximal end of the elongated tube is disposed outside of the proximal end of the sheath, the elongated tube comprises two markings (28), one of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other opening of the sheath (Col. 3, lines 41 – 56), the proximal end of the elongated tube is connected to a pressure transducer (Col. 3, lines 24 - 27). The tubular sheath has an inside peripheral surface and the elongated tube has an outside peripheral

surface, the elongated tube is frictionally received in the tubular sheath (Col. 3, lines 18 –20). In order for the device to perform, fluid communication through the tubular sheath between the inside surface of the tubular sheath and the outside surface of the elongated tube must be prevented. Otherwise, pressure readings would not be obtainable at the multiple sheath openings (20; Col. 4, lines 56 – 65). Kenigsberg discloses the tubular sheath as preferably having an open distal end (Col. 2, line 60). In doing so, Kenigsberg suggests but fails to explicitly disclose the distal end being closed. It is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In the present case, Kenigsberg discloses the distal end “preferably open”, but does not teach away from a closed distal end having an opening adjacent thereto. To the contrary, Kenigsberg teaches that elongated tube (22) as well as tubular members (32, 38) could have an open distal end or a closed distal end with an opening adjacent thereto (Col. 3, lines 22 – 24; Col. 3, line 67 – Col. 4, line 2; Col. 4, lines 15 – 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the open distal end of the tubular sheath as disclosed by Kenigsberg to be a closed distal end with an opening adjacent thereto in that Kenigsberg teaches that an alternative configuration to “preferably open” is a closed end having an opening adjacent thereto (Col. 3, lines 22 – 24; Col. 3, line 67 – Col. 4, line 2; Col. 4, lines 15 – 19). Additionally, Kenigsberg teaches that it is desirable to keep the elongated tube (22) from extending past the distal end of sheath (Col. 3, lines 28 – 31). It would have been obvious to one having ordinary skill in the art to modify the open distal end of the tubular sheath as disclosed by Kenigsberg to be a closed distal end in order to keep the elongated tube (22) from extending past the distal end of the sheath. Kenigsberg discloses a distal portion of the blood pressure measuring device having an exterior surface having a cross-sectional profile of a single circle (Col. 3, lines 61 –

65; Col. 4, lines 9 - 12) by placing member (32) within a suitably modified sheath. However, Kenigsberg fails to specifically disclose how the modification of the sheath would maintain the entire outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath. Peacock, III et al. teach a tubular sheath having multiple lumens positioned within the sidewall of the sheath in order to maintain an outer cross-section and inner cross-section of a single cylinder (Figure 1B). Such a modification of sheath (12) would maintain the necessary engagement between the outside surface of the elongated tube and the inside surface of the outer sheath (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Kenigsberg by forming a lumen in the sidewall of the tubular sheath (12) for the member (32) so as to maintain free movement of the elongated tube (22) within the sheath (12) while preventing fluid communication between the inside surface of the tubular sheath and the outside surface of the elongated tube.

Claims 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent U.S. Patent No. 4,168,703 to Kenigsberg in view of U.S. Patent Application No. 2002/0049402 to Peacock, III et al. as applied to claims 13 and 16 above, and further in view of U.S. Patent No. 6,259,938 to Zarychta et al.

In regards to claims 14 and 19, Kenigsberg in view of Peacock, III et al. fails to disclose the sheath of the pressure monitoring device comprising a radiopaque marker at a distal end thereof. However, Zarychta et al. discloses a pressure monitoring device having comprising a sheath having a radiopaque marker at a distal end thereof (Col. 4, lines 35 – 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sheath as disclosed by Kenigsberg in view of Peacock, III et al. to include a radiopaque marker at a distal end as taught

by Zarychta et al. in order to facilitate positioning of the sheath within the patient (Col. 4, lines 31 – 33).

(10) Response to Argument

Applicant asserts that the combination of Kenigsberg and Peacock, III et al. fails to teach or suggest a tubular sheath having a closed distal end. However, the Examiner disagrees. Kenigsberg states of the tubular sheath (12) at Col. 2, lines 58 – 61:

The sheath 12 has a hollow interior 13 substantially throughout its length and terminates in a distal end 14 which is *preferably open* and in a hollow manipulating body 16 at its proximal end 18.

The disclosure of *preferably open* would lead one having skill in the art to believe that there is a nonpreferred arrangement that would perform equally as well. Kenigsberg later states of elongated tube 22 at Col. 3., lines 22 – 24:

The end 24 is *preferably open*, although an opening could alternatively be provided adjacent thereto.

Of tubular member 32, Kenigsberg states at Col. 3, line 67 – Col. 4, line 2:

The end 34 is *preferably open*, although an opening could alternatively be provided in the member 32 substantially adjacent the end 34.

Additionally, Kenigsberg states of tubular member 38 at Col. 4, lines 15 – 19:

As the description proceeds, however, it will become apparent that the end 40 need not be open if instead an opening is provided in the second member 38 at a position intermediate the proximal and distal ends of the sheath 12.

It is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In the present case, Kenigsberg discloses the distal end “preferably open”, but does not teach away from a closed distal end having an opening adjacent thereto. To the contrary,

Kenigsberg points out specifically where an alternative arrangement to the preferably open end is a closed end having an opening adjacent thereto. As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the preferably open distal end as disclosed by Kenigsberg to be a closed distal end with an opening adjacent thereto in that Kenigsberg teaches such a configuration to be a workable alternative arrangement.

Additionally, Kenigsberg teaches that it is desirable to keep the elongated tube (22) from extending past the distal end of sheath (Col. 3, lines 28 – 31). In response to the Examiner's assertion that it would have been obvious to one having ordinary skill in the art to modify the open distal end of the tubular sheath as disclosed by Kenigsberg to be a closed distal end in order to keep the elongated tube (22) from extending past the distal end of the sheath, Applicant points out that Kenigsberg discloses preventing the overextension of the elongated tube (22) past the distal end (14) by sizing the length of the elongated tube(22) so that the extension beyond the distal end (14) can be halted by the contact of the tapered end (26) with the manipulating body (16). However, the Examiner maintains that another solution known in the art to maintain an inner member from extending past an outer member is by simply closing the distal end of the outer member.

Applicant asserts that the combination of Kenigsberg and Peacock, III et al. does not teach or suggest the exterior of the distal portion of a medical device having a cross-sectional profile of a single circle. Applicant asserts that reference member 32 hinders a cross-sectional profile of the distal portion having a single circle. However, the Examiner disagrees. Kenigsberg states at Col. 3, lines 61 - 65:

Although shown positioned on the surface of the sheath 12 in the drawing, the member 32 may be located within a suitably modified sheath (not shown) provided its placement within the sheath does not interfere with the free movement of the probe 22 therein.

Applicant sets forth two possible configurations for placing the member (32) within the tubular sheath (12). One configuration proposes placing member (32) adjacent elongated tube (22) (See Figure A, Page 14 of Appeal Brief). The second suggested configuration proposes placing member (32) within elongated tube (22) (See Figure B, Page 14 of Appeal Brief). The Examiner agrees with Applicant that each of these configurations would lead to the device being inoperable. However, the Examiner asserts that a third configuration, one where a lumen is formed in the sidewall of the sheath as taught by Peacock, III et al., would be an obvious modification to the device as disclosed by Kenigsberg which would lead to operability of the device as well as the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath. Applicant asserts that the limitation "the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath" is contemplated only by the claimed invention. Additionally, Applicant asserts that Kenigsberg discloses that "movable probe 22 is sized for relatively longitudinal frictionless sliding movement within the interior 13 of sheath 12" (Col. 3, lines 18 – 20) indicating that engagement may not be necessary or even desirable. However, the Examiner disagrees with this conclusion. In order for the device of Kenigsberg to be operable, that is, to make pressure measurements at any desired sheath opening (See Col. 4, lines 57 – 64), the outside peripheral surface of the elongated tube (22) must engage the inside peripheral surface of the tubular sheath. Thus, any suitably modified sheath would need to preserve this aspect of the device.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed

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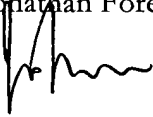
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invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

For the above reasons, it is believed that the rejections should be sustained.

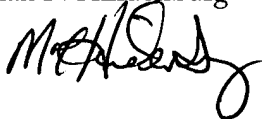
Respectfully submitted,

Jonathan Foreman

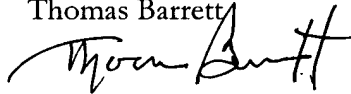
A handwritten signature in black ink, appearing to be 'J Foreman', written over the printed name.

Conferees:

Max F. Hindenburg

A handwritten signature in black ink, appearing to be 'Max Hindenburg', written over the printed name.

Thomas Barrett

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